UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: May 7, 2009

SUBJECT: Label Amendment for Fresh Cab (EPA Reg. #: 82016-1), Containing 2.0% Fir Needle Oil (Active Ingredient). Review of Deficiency Response for Product Performance Study

Decision Number:	403501
DP Number:	364648
EPA File Symbol Number:	82016-1
Chemical Class:	Biochemical
PC Codes:	129035
Tolerance Exemption:	40 CFR 180.
MRID Numbers:	47611701

From: Manying Xue, Chemist
Clara Fuentes, Biologist
BPB/BPPD (7511P)

To: John Fournier, Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

In response to deficiency cited in BPPD's letter, dated 04/16/09, on behalf of EARTH-KIND, Inc. DBA Crane Creek Gardens, Pither Consulting, LLC has submitted a letter regarding the product performance study for label amendment to increase the interval of efficacy from 30days to 100 days for Fresh Cab (EPA Reg. #: 82016-1) containing 2% of fir needle oil (the active ingredient).

BPPD has reviewed and evaluated the deficiency response from the registrant for the EP, Fresh Cab. The decisions are made to reflect the current OPP policies.

Recommendations and Conclusions

1. The registrant has adequately identified the substance used for testing is the same as the product proposed fro registration.

2. Food catching is not the best method for assessing repellency for the following reasons:

    a) The mice can go in the treated room, grab the food and leave without spending time there, or
    b) Alternatively, they can stay in the room eating without being repelled, which mean that the product works more as an attractant than a repellent.
    c) This may sound as an unlikely possibility, but it needs to be tested to know for sure.
    d) Statistically, what has been measured is the difference in the amount of food found between the treated and untreated rooms, and this measure is used as an indirect measure of mice activity. Again, this is an indirect measure of behavior.
    e) Behavior needs to be observed. It is more qualitative than quantitative in nature.
    f) The registrant states that the mice were observed to spend more time (88%) in the control room than in the treated room (12%).
    g) The question remains how long and for how often were these observations?

3. The registrant explains that observing the mice for a longer period of time will be disruptive, and they are correct about that. Here is a suggestion: do the study without coming into the room; mice can be observed through windows. These types of studies are conducted under red light in the dark so that animals do not perceive human presence.

4. The registrant refers to 10 days of observations as replications. Were the same mice used over this long period of time? In this study, the mice (10 or 20 per treatment) are the experimental units assigned randomly to 2 treatments (control and treated room). So the treatments are replicated 10 or 20 times per trial. Observations were collected for a period of 10 days. If different mice had been used every 5 days, for example, the experiment would have been replicated twice. If different mice had been used every 2 days for a total of 10 observations, the study would have been replicated 5 times, and so on. The study was not replicated if it was run only once using the same mice.

5. Using the same animals over long periods of time is not recommended. They can be acclimatized to the experimental conditions, which could affect their behavior, and compromise the results.

cc: J.Fournier; BPPD Chron File; OHAD/ARS
M. Xue, BPPD, 05/07/09